MAY 21 2003

F: 510(k) Summary
(K031079)

March 31, 2003

Company:	Gyrus Medical, Inc. 6655Wedgwood Road Maple Grove, MN 55311-3602 Tel. No. (763) 416-3000 FAX. No. (763) 416-3070
Contact:	Mercedes Bayani Director, Regulatory Affairs

Common/Usual Name:	Electrosurgical Instruments
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)
Proprietary Name:	Everest Bipolar Needle Electrode and Gyrus Bipolar Needle Electrode

The device is a Class II medical device. The Bipolar Needle Electrode is a modification to the predicate device cleared under K904993. The bipolar Needle Electrodes are identical in construction (with the exception of shaft length) and in component materials when compared to the predicate device. The cutting electrode is electrically isolated from the return electrode, enabling one electrode to act as a return electrode, eliminating the need for a return pad. The modification has not altered the fundamental technology of the predicate device cleared under K904993. The intended use, electrosurgical cutting, and mechanical dissection are identical to the predicate devices cleared under K904993. The energy source, bipolar electrosurgical energy, is the same energy type as used for the predicate devices.

In conclusion, as the design, materials of construction, function and intended use of the modified bipolar needle electrode is similar to that of the predicate devices currently cleared, Gyrus Medical Inc. believes that no new issues of safety and effectiveness are raised and that the submitted device is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2003

Ms. Mercedes Bayani
Director, Regulatory Affairs
Gyrus Medical, Inc.
6655 Wedgwood Road
Maple Grove, Minnesota 55311

Re: K031079
Trade/Device Name: Everest Bipolar Needle Electrode and Gyrus Bipolar Needle Electrode
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 31, 2003
Received: April 24, 2003

Dear Ms. Bayani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031079

Device Name: Everest Bipolar Needle Electrode & Gyrus Bipolar Needle Electrode

Indications for Use:

Electrosurgical cutting and mechanical dissection of tissue, during the performance of laparoscopic and general surgical procedures.

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K031079